K052420

GyNOVA, LLC

APR 6 2006

510(k) August 24, 2005

510 (k) SUMMARY:

G-Spec™ Articulated Weighted Vaginal Speculum

1. GyNOVA, L.L.C.
698 Middle Turnpike East
Manchester, CT 06040

Contact Person: Don Guinan
Date Summary Prepared: August 24, 2005

2. Trade or Proprietary Name:

G-Spec™ Articulated Weighted Vaginal Speculum

3. Common Name:

Vaginal Speculum

4. Classified Name:

Nonmetal vaginal speculum
21 CFR 884.4530

5. Product Code: 85 HIB

Predicate Devices:
Medisul Disposable Vaginal Speculum, Marketing Perspectives, Inc.(k000414)
Disposable Vaginal Speculum, Medical Action Industries, Inc. (k0022948)
Kentex Disposable Vaginal Speculum, Kentron Health Care, k030693
Vag O Speculum, Panatrex, Inc. (k043950)
Plastic Vaginal Speculum, Astralite Corp. (k# unknown)
Auvard Weighted Vaginal Speculum, Cooper Surgical (exempt)

(4) Description of Device:

G-Spec™ Articulated Weighted Vaginal Speculum is supplied with single use disposable blades that attached to a 2 pound stainless steel weighted speculum handle. The disposable blades are supplied in three sizes:

9,11, and 13 centimeters

And can be set to three positions relative to the weighted handle:

90, 80, and 70 degrees

The disposable blades snap fit into the reusable weighted speculum handle and are discarded after each use. The reusable weighted speculum handle is reusable and may be cleaned and resterilized.

(5) Intended Use:

The G-SPEC™ Articulated Weighted Vaginal Speculum is intended for use to retract and expose the interior of the vagina during general diagnostic and therapeutic gynecological and obstetric procedures.

(6) Technolgical Characteristics:

The G-SPEC™ Articulated Weighted Vaginal Speculum consists of a single use plastic blade which attaches to a reusable weighted stainless steel handle. The blades are provided in three sizes and may be adjusted to four positions during use.

(7) Conclusion:

The G-SPEC™ Articulated Weighted Vaginal Speculum has the same intended use and the same basic technology as the predicates identified in the premarket notification submission. The new device contains in some combination similar/same features, materials, and design as the predicates and does not pose any new questions concerning safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 6 2006

Don Guinan, Jr.
Managing Director/Principal Owner
GyNOVA LLC
698 Middle Turnpike East
MANCHESTER CT 06040

Re: K052420
Trade/Device Name: G-SPEC™ Articulated Weighted Vaginal Speculum
Regulation Number: 21 CFR §884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HIB
Dated: March 6, 2006
Received: March 7, 2006

Dear Mr. Guinan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

GyNOVA, LLC

510(k) August 29, 2005

Indications for Use

510(k) Number (if known): K052420

Device Name: G-SPEC™ Articulated Weighted Vaginal Speculum

Indications for Use:

To retract and expose the interior of the vagina during general diagnostic and therapeutic gynecological and obstetric procedures.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052420